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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,096	05/11/2007	David W. Boykin	1523/2 PCT/US	6354
25297 7590 12/23/2010 JENKINS, WILSON, TAYLOR & HUNT, P. A. 3100 Tower Blvd. Suite 1200 DURHAM, NC 27707				
EXAMINER				
STOCKTON, LAURA LYNNE				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
12/23/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,096

Applicant(s)

DAVID W. BOYKIN

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18 and 20-43 is/are pending in the application.
- 4a) Of the above claim(s) 2-15 and 30-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 20-27 and 29 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

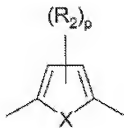
Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/14/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

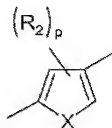
requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Note: Subject matter wherein **L** represents either



, as shown above, or



and **X** is

S, in both instances, in formula (I) has been examined in elected Group IV.

Subject matter not embraced by elected Group IV and Claims 2-15 and 30-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no

allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 12, 2010.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on October 14, 2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicant's amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 lacks antecedent basis from claim 1.

Response to Arguments

Applicant's arguments filed October 14, 2010 have been fully considered but they are not persuasive. Applicant argues that one skilled in the art would understand that some of the compounds encompassed by independent claim 1 are prodrugs and indicates page 33 of the instant specification.

Applicant's argument has been considered but has not been found persuasive because the "prodrug" is not

limited to only prodrugs of amidino and guanidine as disclosed in the instant specification, but any prodrug presently known. Therefore, Applicant's argument is not persuasive.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Since the instant application claims the benefit under 35 USC § 119(e) of Provisional application

60/551,089 filed March 8, 2004, the disclosure in the provisional applications was reviewed because of the possibility of intervening art. It was found that Provisional application 60/551,089 fails to provide adequate support for the entire scope of the instant claimed invention. See the definitions of R_1 and R_3 in the instant application. Therefore, the instant claimed invention can only rely on the filing date of the 371 application, which is March 7, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 16, 18, 20-22, 24-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallena et al. {Journal of the American Chemical Society, September 2004, 126(42), pages 13659-13669} in view of the teachings in Goldberg et al. {U.S. Patent 2,641,601}.

***Determination of the scope and content of the prior art (MPEP
§2141.01)***

Applicant claims a method of treating trichomoniasis by administering diamidine containing compounds. Mallena et al. teach that diamidine compounds are useful in treating parasitic diseases (page 13659) and that compound DB75 has been found to have useful properties (page 13660, first column). Mallena et al. disclose such compounds as DB818 and DB75 (Figure 1 on page 13659).

***Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)***

Mallena et al. do not disclose that compounds DB818 and DB75 are useful for treating trichomoniasis.

However, Goldberg et al. (see entire document; particularly column 1; and especially Example 14 in columns 11-12) teach that 2,5-diphenylfurans are useful as anti-trichomonas compounds.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would thus be motivated to prepare products disclosed in Mallena et al. especially in view of the teachings in Goldberg et al. to arrive at the instant diamidine containing products with the expectation of obtaining products which would be useful in treating trichomoniasis. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Allowable Subject Matter

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on October 14, 2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed,

and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 2-15 and 30-43 drawn to an invention nonelected without traverse in the reply filed on April 12, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on

(571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
Laura L. Stockton, Ph.D.
Primary Examiner, Art Unit 1626
Work Group 1620
Technology Center 1600

December 21, 2010